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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,663	02/06/2002	Chuan Li		9010

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,663	LI, CHUAN	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *63-70* is/are allowed.

6)☐ Claim(s) *57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani (US Patent no. 3,880,814).

Mizutani teaches of a composition or sample solution comprising at least three polypeptides of different known size and of different known amounts. The sample solution comprises 15 mg of the polypeptide conalbumin having a molecular weight or size of 87,000, 4 mg of ovalbumin having a molecular weight or size of 46,000, and 7 mg of lysozyme having a molecular weight or size of 14,600. See lines 6-13 in column 4 of Mizutani. The three polypeptides in the composition taught by Mizutani are the same polypeptides as taught in Example 1 on page 11 of the instant specification, and therefore, the size of the polypeptides disclosed by Mizutani would inherently cover a range that is separable by polyacrylamide gel

electrophoresis, and the amounts of the polypeptides taught by Mizutani would inherently cover a range that is detectable by a given protein detection assay.

Mizutani fails to teach that the polypeptides conalbumin, ovalbumin and lysozyme are present within a kit, and fail to teach that in preparing the solution containing the three polypeptides, the amounts of the polypeptides are estimated using a detection assay with different amounts of a standard protein such as BSA. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the polypeptides in the solution taught by Mizutani into a kit so as to have all of the polypeptides present in a single container in the correct amount in order to facilitate the quick and easy performance of the method taught by Mizutani. It also would have been obvious to one of ordinary skill in the art at the time of the instant invention to estimate the recited amounts of the polypeptides taught by Mizutani (15 mg conalbumin, 4 mg ovalbumin and 7 mg lysozyme) using a detection assay with different amounts of a standard protein such as BSA since it is common knowledge in the art of protein assays to use a standard such as BSA in different known amounts in order to determine the amounts of polypeptides in an unknown sample, and to express the amounts of the polypeptides as equivalent amounts of the standard protein, as evidenced by Applicant's own admission in the response received on February 15, 2006.

4. Claims 63-70 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests a method for estimating both the size and amount of a polypeptide in a protein sample by electrophoresing simultaneously in separate lanes on a gel the protein sample and a protein standard containing at least three different polypeptides therein having different sizes from one another and being present in different amounts from one another,

wherein the amounts of the polypeptides in the standard are expressed as an equivalent amount of a standard protein, detecting the polypeptides on the gel with a detection assay to obtain the relative positions and detection intensities of the polypeptides, comparing the relative positions of the polypeptides of the protein standard with the relative position of the polypeptide in the protein sample to estimate its size, and comparing the relative detecting intensity of the polypeptides of the protein standard with the relative detecting intensity of the polypeptide in the protein sample to estimate its amount.

5. Applicant's arguments filed June 5, 2007 have been fully considered but they are not persuasive.

Applicant argues that the statements made in the third paragraph of the response mailed on February 15, 2006 need to be changed to accurately reflect Applicant's meaning since it is not common knowledge in the art that the staining intensities of the protein bands in a protein standard reflect their quantities. In response to this request to change the information submitted in the response filed on February 15, 2006, it is noted that Applicant is trying to take back his own admission, and this clearly cannot be done. The Examiner has interpreted Applicant's previous comments in the response filed February 15, 2006 and in the response filed February 9, 2007 as an admission that it is known in the art to determine the quantity or amount of a polypeptide in a test sample by comparing the relative staining intensity of the polypeptide on a gel with the relative staining intensity of different amounts of a known protein such as BSA on the same gel. This teaching is known in the prior art, as evidenced by the teaching of Houghton et al (US 6,168,946, previously cited), where is states in lines 37-46 of column 13 that protein concentration is estimated by the comparison of the staining intensity of a protein band of a test

sample on a polyacrylamide gel to the staining intensity of a series of known amounts of molecular weight markers also on the gel. Since this is a common practice in the prior art, the Examiner is saying in the rejection of the claims under 35 USC 103 as being obvious over Mizutani that it would have been obvious to one of ordinary skill in the art at the time of the instant invention to individually and separately determine the amounts of conalbumin, ovalbumin and lysozyme, before being blended together into the blended composition disclosed by Mizutani, by running each of the conalbumin, ovalbumin and lysozyme on a gel separately along with different amounts of a protein standard such as BSA, and individually comparing the staining intensity of conalbumin, ovalbumin and lysozyme to the different amounts of the protein standard in order to estimate their individual quantities. Once the individual quantities of each of the proteins included in the composition taught by Mizutani are known and determined by this well-known method, they can be combined into the single composition containing all three polypeptides.

Applicant argues the previous rejections of the claims made in the Office action mailed on March 6, 2007 under 35 USC 103 as being obvious in view of Mizutani by stating that Mizutani fails to teach of using the polypeptides taught therein together as a protein standard on a gel in order to determine the size and quantity of a protein simultaneously since the staining intensities of the polypeptides do not reflect their quantities. In response to Applicant's arguments, it is noted that Applicant's arguments are all directed to the method of use or intended use of the protein standard. This method of use, as recited in instant claims 63-70, has been indicated to be allowable over the prior art of record since Applicant's new principles of operation, as outlined in the response received on July 20, 2006, are persuasive regarding this

method. However, Applicant's arguments are not persuasive for claims 57-62 since claims 61-62 are directed simply to a product/composition containing three different size polypeptides in each of three different amounts. The composition as taught in lines 6-13 of column 4 in Mizutani is the same exact product as recited in claims 61-62. The fact that a composition is intended for a new and unobvious use does not render the composition itself patentable. See In re Pearson, 181 USPQ 641 (CCPA 1974). In addition, claim 57 is directed to a method of preparing such a product by combining three different size polypeptides in three different amounts, which is also what Mizutani teaches. It would have been obvious to one of ordinary skill in the art to separately determine the amounts of each of the polypeptides in the product taught by Mizutani with a detection assay by comparing the relative staining intensities of the polypeptides on a gel with the relative staining intensities of different amounts of known proteins such as BSA or lysozyme since it is common knowledge in the art of protein assays to use a standard such as BSA in different known amounts in order to determine the amounts of polypeptides in an unknown sample, and to express the amounts of the polypeptides as equivalent amounts of the standard protein, as evidenced by Applicant's own admission in the response received on February 15, 2006 and on pages 2-3 of the response received on February 9, 2007. All that claims 57 and 61-62 require is a mixture of three different polypeptides of different sizes and in different amounts. In addition, these claims require that the quantity of the polypeptides be estimated by comparison to a standard protein such as BSA or lysozyme in a detection assay (i.e. separating the polypeptides on a gel and staining with a dye such as Coomassie Blue). Applicant admits on pages 2-3 of the response received on February 9, 2007 that a protein detection assay using BSA as a standard material is most likely used to estimate the

amounts of the polypeptides conalbumin, ovalbumin and lysozyme in the polypeptide mixture taught by Mizutani. Therefore, the reference to Mizutani meets all of the limitations recited in instant claims 57-62

Applicant argues that since the method of using the protein standard of the instant invention is not obvious, then the claimed quantitative protein standard and method of making are also not obvious. In response to this argument, it is noted that claims directed to a product or composition are patentably distinct from claims directed to a method of using a product or composition. Product claims are patentably judged by what components they are comprised of, not based upon the methods the product can be used in or what the product is used for. Since the product taught by Mizutani contains all of the components recited in instant claims 61-62, the teaching of Mizutani renders obvious the product recited in claims 61-62 for the reasons set forth above in the rejection, even though the product of Mizutani is used in a different method than used by Applicant. Method of making claims are patentably judged by the specific steps used to formulate the composition, not upon other intended uses of the product. Since instant claims 57-60 only set forth steps of combining different polypeptides having different sizes and amounts from one another into a single composition, the steps taught by Mizutani render obvious these claims for the reasons set forth above in the rejection. Claims 57-60 do not contain any steps directed to using the protein standard to estimate the size and amount of polypeptides in an unknown protein sample.

Applicant also argues that the method of making and using the claimed quantitative protein standard are integral parts of the invention since the same staining assay has to be used in both detecting and estimating the quantity of each of the polypeptides in the protein standard as

is used in detecting and estimating the quantity of polypeptides in an unknown protein sample by comparing the responses of the unknown sample with the protein standard. In response to this argument, it is noted that instant claims 57 and 61-62 do not recite that the staining assay used in detecting and estimating the quantity of each of the polypeptides in the protein standard has to be the same as the staining assay applied when using the protein standard to estimate the size and amount of polypeptides in an unknown protein sample. Claims 57 and 61-62 only recite a single detection assay used to detect and estimate the quantity of the polypeptides in the standard, and this detection assay could be any of the known protein assays used for many years (i.e. Coomassie Blue, Fast Green, silver, fluorescamine staining, etc.) to estimate the quantity of an unknown polypeptide. Claims 57 and 61-62 do not recite any other detection assays, or how the method of making the protein standard is integral or related to a method of using the protein standard by any common staining assay.

Applicant argues that the invention solves a long-felt, long-existing but unsolved need. In response to this argument, it is noted that Applicant's argument with regards to solving a long-felt need is persuasive with regards to the method of using the protein standard to estimate both the size and amounts of polypeptides in a protein sample. However, since the reference to Mizutani teaches of a composition or product containing all of the sample polypeptides in different amounts and a method for making such a composition, the claims directed to the product and method for making (i.e. claims 57-62) do not solve any long-felt need since the product and method for making are already known.

Applicant also argues that no one has implemented the instant invention for over 30 years, thus rendering it non-obvious. This argument is persuasive for the method of using the

protein standard, as indicated above in the reasons for allowance. However, this argument is not persuasive for the product claims 61-62 and method for making claims 57-62 since Mizutani teaches of such a product and a method for making.

In conclusion, claims 57-62 remain rejected as set forth above, and claims 63-70 are allowable over the prior art of record.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 8, 2007

Maureen M. Wallenhorst
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